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Applicant : Giannoukakis

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For : GENE TRANSFER TO PANCREATIC CELLS FOR PREVENTION OF ISLET DYSFUNCTION

DECLARATION OF DR. PAUL ROBBINS
UNDER 37 C.F.R. '132

I hereby certify that this paper is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on: September 25, 2002

Carmella L. Stephens — Attorney Name
Carmella L. Stephens — Signature
41,328 — PTO Registration No.
September 25, 2002 — Date of Signature

Assistant Commissioner for Patents
Washington, D.C. 20231

I, PAUL ROBBINS, do declare:

1. I am co-inventor of the invention disclosed in the above-identified application. A copy of my Curriculum Vitae is attached herewith as Exhibit A.

2. The invention disclosed in the above identified application relates to methods and compositions for inhibiting pancreatic islet ß-cell dysfunction. Specifically, the invention relates to the transfer of nucleic acid molecules encoding inhibitors of interleukin-1

into pancreatic islet ß-cells. Such pancreatic islet ß-cells can then be transplanted into a host recipient susceptible to a pancreatic disorder for inhibition of pancreatic islet ß-cells dysfunction.

3. Insulin-dependent diabetes mellitus (IDDM) is characterized by a local inflammatory reaction in and around the islets of Langerhans followed by selective destruction of pancreatic islet ß-cells. In both humans and the non-obese diabetic (NOD) mouse, the immunopathology is characterized by an early onset insulitis with a significant proportion of the invading cells consisting of T-lymphocytes which are believed to directly damage ß-cells by secreting proinflammatory cytokines. Such cytokines include interleukin-1ß (IL-1ß) which has been shown to be the initiating cytokine directly responsible for the impairment of glucose-stimulated insulin production in mouse and human islets.

3. Experiments were conducted to test whether recombinant expression of an IL-1ß inhibitor in pancreatic islet ß-cells could reduce pancreatic islet ß-cell dysfunction *in vivo*. The experiments were conducted in NOD mice, a strain of mice susceptible to autoimmune mediated diabetes.

4. As indicated in Figure 1, pancreatic islet ß-cells were derived from NOD mice and transfected with recombinant adenovirus or lentivirus vectors expressing either a control LacZ gene (Ad-LacZ or LtV-LacZ) or the interleukin-1 receptor antagonist

protein (IRAP) (Ad-IRAP or LtV-IRAP). IRAP is known to be an inhibitor of IL-1ß activity.

5. A total of approximately 400 transduced pancreatic islets were then transplanted into streptozotocin treated NOD mice: 200 control lacZ transduced islets transplanted under one kidney capsule and 200 IRAP transduced islets transplanted under the opposite kidney capsule. Streptozotocin is a compound which is known to selectively kill pancreatic islet ß-cells. Thus, the experiment is designed to test the protection afforded to pancreatic islet ß-cells expressing an inhibitor of IL-1ß activity, *i.e.*, IRAP, when transplanted into an animal model susceptible to development of diabetes.

6. When the transplanted animals began to show signs of diabetes, the animals were sacrificed and the histology of the transplanted islets was examined. Figures 2 and 3 show that Ad-IRAP and LtV-IRAP, respectively, are capable of reducing islet destruction in transplanted NOD mice. Panels A and B are stained for insulin, using anti-insulin antibodies, and demonstrate greater insulin expression in the animals receiving transplanted pancreatic islet ß-cells transfected with vectors expressing IRAP (Ad-IRAP and LtV-IRAP) versus control cells (Ad-LacZ and LtV-LacZ). In addition, as depicted in panels C and D there is less white blood cell infiltration around the islets in the animals receiving cells expressing IRAP. The data depicted in Figures 2 and 3 demonstrate that expression of an IL-1ß inhibitor is capable of reducing *in vivo* pancreatic islet ß-cell destruction.

7. In a second set of experiments, NOD animal derived pancreatic islet ß-cells were transfected with recombinant adenovirus vectors genetically engineered to express the LacZ, or IRAP genes. The transfected islet cells were then transplanted into streptozotocin treated NOD *SCID* mice (Figure 4). As indicated above, such mice do not have functional pancreatic islet ß-cells due to streptozotocin mediated destruction. In addition, since the mice are *SCID* mice, they do not have a functional immune system. Once the transfected pancreatic islets had been transplanted into the NOD SCID animals, the animals were challenged with spleen cells derived from a diabetic mouse. Such spleen cells will contain a population of T lymphocytes primed to attack pancreatic islet ß-cells.

8. Figure 5 is a summary of the data derived from the T-lymphocyte challenged transplants. The data is presented as number of survival days following T-lymphocyte challenge where n represents the number of animals studied. As indicated, the animals expressing IRAP survived for longer periods of time than the controls, **i.e.**, 37 days (Ad-IRAP) versus 27 days (Ad-LacZ). Thus, the data indicates *in vivo* reduction in pancreatic islet cell destruction in animals expressing an inhibitor of IL-1ß activity.

6. I hereby declare further that all statements made herein by my own knowledge are true and that all statements made on information and belief are believed to be true and further that I make these statements with the knowledge that willful false statements

and the like are punishable by fine or imprisonment, or both, under ' 1001 of Title 18 of the united States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing therein.

Dated: 9/24/02

Dr. Paul Robbins

Transplantation of Genetically Modified Islets

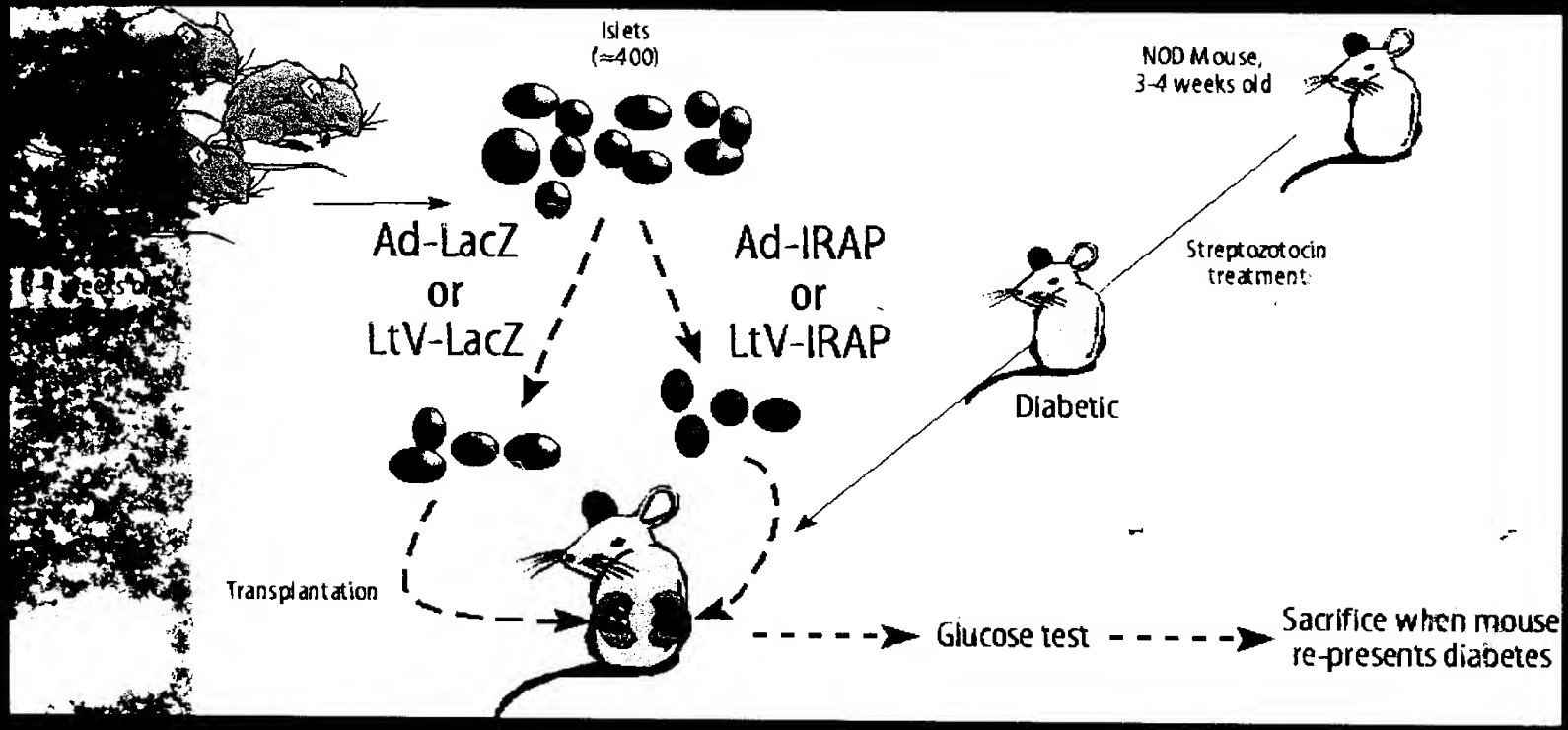

Figure 1

Ad-IRAP Blocks Islet Destruction in Transplanted NOD Mice

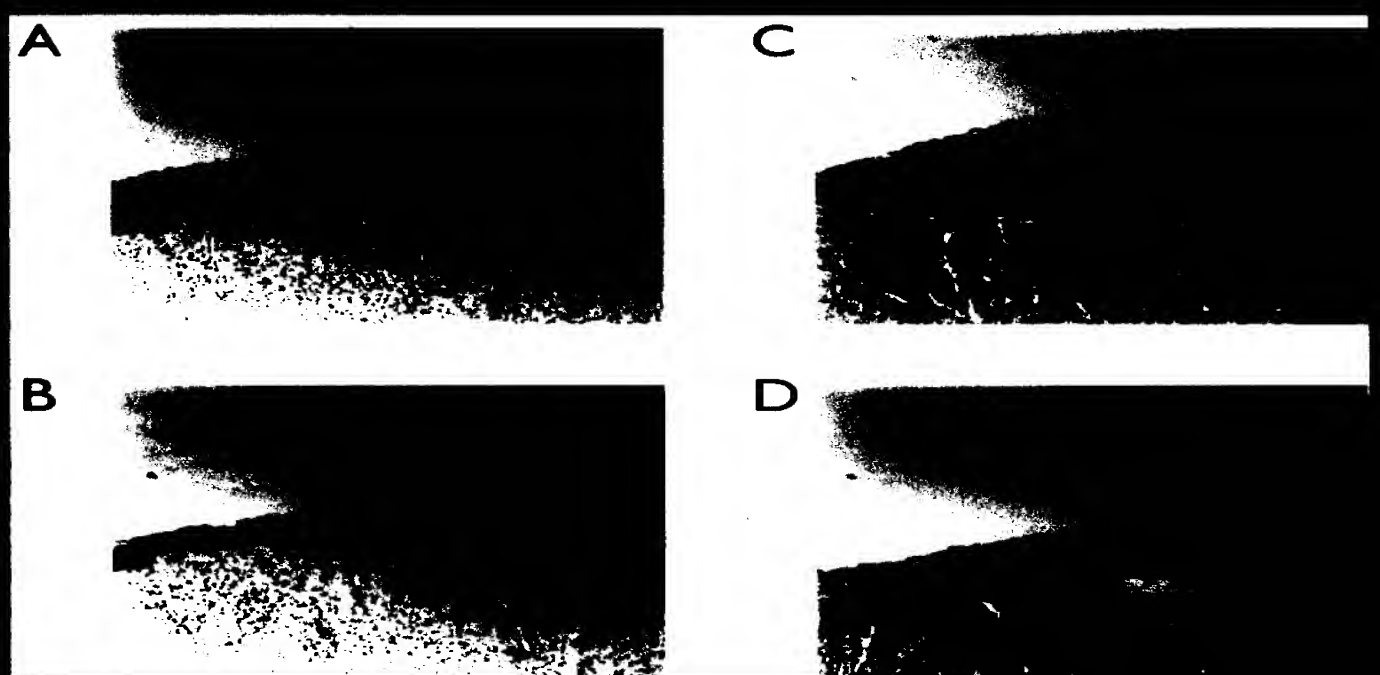

Figure 2

LtV-IRAP Blocks Islet Destruction in Transplanted NOD Mice

Figure 3

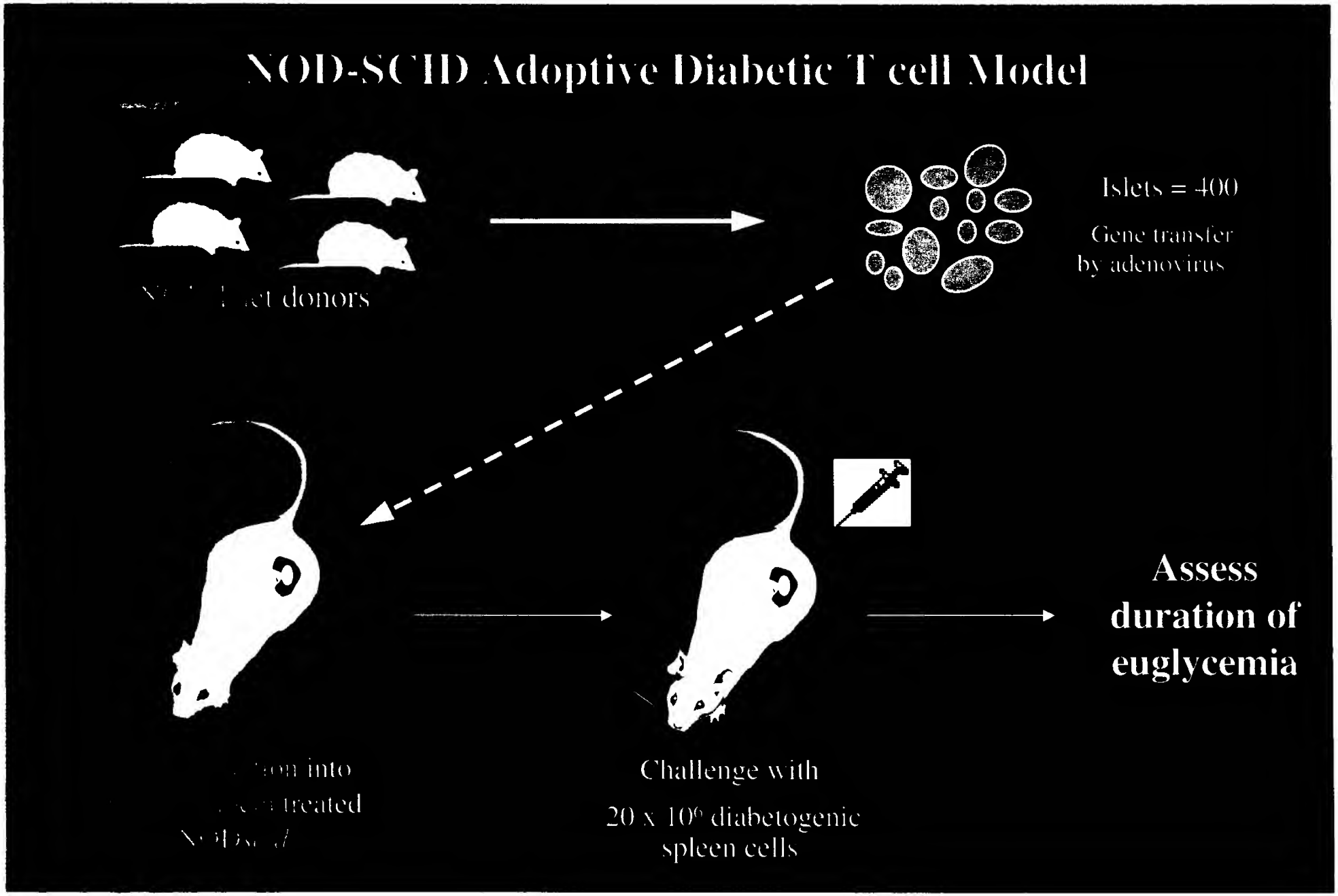
NOD-SCID Adoptive Diabetic T cell Model
Islets = 400
Gene transfer
by adenovirus
Assess
duration of
euglycemia
Challenge with
20 x 10⁶ diabetogenic
spleen cells

Figure 4

Summary of T cell Challenged Transplants

Islet Modification	n	mean ± sd
Unmodified	11	31 ± 9
Ad-LacZ	10	27 ± 12
Ad-IRAP	9	37 ± 14
Non-Tx	27	29 ± 6

Figure 5

CURRICULUM VITAE

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Education

Haverford College Haverford, Pennsylvania, 1976-1980	B.A.	Biology
University of California Berkeley, California, 1980-1985	Ph.D.	Molecular Biology

Positions Held

Postdoctoral Fellow, Whitehead Institute for Biomedical Research, Cambridge, Massachusetts, 1986-1990

Assistant Professor, Department of Molecular Genetics and Biochemistry, University of Pittsburgh School of Medicine, 1990-1995

Director, Vector Core Facility, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania 1991-present

Associate Professor (with tenure), Department of Molecular Genetics and Biochemistry, University of Pittsburgh School of Medicine, 1996-1999

Interim Director, Molecular and Cellular Oncology Program, University of Pittsburgh Cancer Institute, 1997-2001

Professor, Department of Molecular Genetics and Biochemistry, University of Pittsburgh School of Medicine (2000-present)

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125. Robbins, P. D., Gambotto, A. and Storkus, W. J. (2002) Cytokine gene transfer in *The cytokine Handbook*, 4th Edition, M. Lotze and A Thomson, ed, Academic Press, in press

126. Robbins, P. D., Chernajovsky, Y and Evans, C. H. (2003) Rheumatoid arthritis in *Gene Therapy for Autoimmune disease*, in preparation

127. Robbins, P. D., Chernajovsky, Y and Evans, C. H. (2003) Gene therapy for arthritis in *Gene Therapy of Autoimmune Disease*, G. Prud'homme, ed, Landes Biosciences, in preparation

128. Evans, C. H. and Robbins, P. D. (2002) Gene therapy in *The Year in Rheumatology*. J. Gregory, ed., submitted

129. Robbins, P. D., Ghivizzani, S. C., Oligino, T., Mi, Z., and Evans, C. H. (2002) Vectors for gene and protein transfer for orthopaedic applications. *Molecular Biology of Orthopaedics*, in press.

130. Ghivizzani, S. C., Gouze, E., Robbins, P. D. and Evans, C. H. (2002) Gene delivery approaches for treating rheumatoid arthritis. *Molecular Biology of Orthopaedics*, in press

131. Evans, C. H., Ghivizzani, S. C., Herdon, J. H., and Robbins, P. D. (2002) Gene therapy for the treatment of orthopaedic diseases. Part 1: Basic principles and development of human gene therapy. *J. American Academy of Orthopaedic Surgeon*, in press

Book Reviews

1. Robbins, P.D. and S. A. Khan. (1992) Review of **In Focus: DNA Replication** by R. l. P. Adams for the *Quarterly Review of Biology* **67**:354.

2. Robbins, P. D. (1997) Review of **The Internet Book of Gene Therapy: Cancer Therapeutics**, R. Sobol and K Scanlon, Eds., *Nature Med.* **3**:806

3. Robbins, P. D. (1999) Review of **Adenovirus Methods and Protocols**, W. Wold, Ed., Human Press, 1999 for *ASM News*. In press

Books

1. Robbins, P. D. (1996) Editor. *Gene Therapy Protocols* Humana Press, Inc., Totowa, N. J., 1996

2. Evans, C. H. and P. D. Robbins, editors, (2000) *Gene Therapy for Inflammatory Diseases*, Birhkauser Verlag, Basel-Boston-Berlin

3. Robbins, P. D. and C. H. Evans, editors, (1999) section on Gene Therapy for Arthritis, for *Innovative Therapies and Diagnostics for Arthritis*, Telesymposia Proceedings, Prous Science, Barcelona, Spain.

4. Evans, C. H. and P. D. Robbins (2002) *Gene Therapy for Arthritis*, R. G. Landes Co, Austin, Tx. in preparation.

5. Robbins, P. D., and Dowdy, S, Editors (2003) Protein Transduction: Characterization, Optimization and Application. Kluwer Press, in preparation

Other Publications

1. Robbins, P. D. (1985) Regulation elements in eucaryotic gene expression. Thesis. University of California, Berkeley, CA.

Grant Support

Active

5R01 CA55227-11 (Robbins) 08/01/98-06/30/03 20%
NIH/NCI $154,503
Regulation of Transcription by the Retinoblastoma Anti-oncogene

The major goal of this project is to understand how the Rb tumor suppressor regulates transcription.

N01-AR-6-2225 (Robbins) 09/30/96-09/29/01 15%
NIH/NIAMS $308,426
Gene Therapy for Rheumatic and Skin Diseases

The overall aim of this contract is to use intra-articular gene transfer methodology to establish novel models of disease with which to access the role of specific proteins and agents in the pathogenesis of arthritis. **Not currently up for renewal.**

5P01 CA73743-03 (Lotze) 01/01/98-12/31/03 5%
NIH/NCI $75,398
Dendritic Cell Biology and Therapy
Vector Core

2P01 DK44935-07A1 (Glorioso) 07/01/99-06/30/04
NIH/NIDDK
Model Systems Toward Development of Human Gene Therapy

Project 2	$112,000	10%
Virus Vector Core	$65,806	5%
Administrative Core	$37,000	5%

The role of the vector core in the model systems for development of human gene therapy program will be to construct and provide vectors expressing the appropriate genes for the proposed experiments. Administrative core deals with overall project management. The project studies the hypothesis that introduction of adenoviral vectors carrying vIL-10 into the intra- and peri-articular regions of the arthritic paws of mice results in the transduction of a leukocyte, probably a dendritic cell, with the ability to suppress disease.

JDFI (Trucco) 10/01/99-09/30/04
Juvenile Diabetes Foundation $130,044 (core only) 5%
$99,668 (project) 10%
Synergy of Gene Therapy and Transplantation to Foster the Diabetes Cure

ROBBIN00G0 (Robbins) 04/01/00-03/31/02 5%
Cystic Fibrosis Foundation $55,272
Identification of Peptides that Facilitate Internalization into Airway Epithelial Cells

The experiments outlined in this proposal should lead to identification of novel peptides that facilitate more efficient internalization into polarized epithelial cells that may be highly useful for improving the efficiency of gene transfer to human airway for treatment of cystic fibrosis by gene therapy.

MDA (Huard) 07/01/00-06/30/03 5%
Muscular Dystrophy Assn. $91,486
Development of Approaches to Facilitate Expansion and Transplantation of Allogeneic Muscle Derived Stem Cells

1U01 HL66949-01 (Glorioso) 09/28/00-08/31/05 5%

NIH/NHLBI $240,086
Supplement to Cardiovascular Gene Therapy Center Grant for Preclinical Vector Core

The primary objective of this portion of the cooperative agreement is to produce preclinical vectors for the principal investigators on the Cardiovascular Gene Therapy Center grant.

NIH (Rinaldo) 09/30/98-08/31/03 5%
5P01 AI43664-03 $51,329 (Core only)
Antigen delivery for adjuvant HIV immunotherapy – Vector core
The major goal of this project is to provide vectors for adjuvant HIV immunotherapy.

NIH (Herberman) 08/01/99-07/31/04 5%
5P30 CA47904-13 $60,087
Cancer Center Support Grant – Vector Core
The major goal of this project is to provide vectors to the members of the Cancer Center.

Maxygen Incorporated 08/01/01-07/31/02
$85,000
Testing of "evolved" genes for regulating the immune response.

R21 DK62622 (Robbins) 9/30/02-9/29/04 10%
NIH/DK $100,000
Analysis of peptide transduction to islets to improve function and viability

Pending

PO1 NIH/NCI (Storkus) 07/01/01-06/30/06
Cytokine Mediated gene therapy of Cancer
Project 3 (PI) $180,000 10%
Virus Vector Core (Co-PI) $65,000 5%
Administrative Core (Co-PI) $80,000 5%

The role of the vector core in the P01 is to develop vectors for cytokine gene therapy of cancer. Administrative core deals with overall project management. The project studies the ability of gene transfer of IL-18 and the IL-1 homologue IL-1H4 to stimulate the anti-tumor response.

R01 AR47828A1 (Robbins) 7/01/02-6/30/07 10%
NIH/NIAMS $225,000
Application of peptide transduction domains for the treatment of hyperplastic synovium.

R01 CA97160 (Robbins) 7/01/02-6/30/07 10%
NIH/NCI $225,000
Analysis of the anti-tumor effects of IL-18 and its homolog IL-1H4

Department and University Committees

Faculty Search Committee, Department of Molecular Genetics and Biochemistry, 1992-present
Co-Chairman, Departmental Seminar Series, 1992-1997
Member, Pittsburgh Cancer Institute, 1992-present
Director, Vector Core Facility, 1991-present
Institutional Biosafety Committee, Member, 1993-present
Organizer of 1993 Committee for Virology Symposium on Oncogenes, 1993
Pittsburgh Advisory Board, First International Congress of the Cell Transplant Society, 1991

Advisory Committee, Human Gene Therapy Applications Laboratory, 1993-present
Member, Internal Competitive Research Grant Review Committee, 1996,1997, 1998, 1999
Search Committee for Molecular Oncologist, UPCI, 1996-97
Evaluation Committee, Interdisciplinary Graduate Program (1997-)
MD/Ph.D. Supervisory Committee (1997-)
Recruiting Committee, Molecular Virology and Microbiology Program (1997-)
Evaluation Committee, Biochemistry and Molecular Genetics Graduate Program (1997-)
Interim Co-Director, Molecular and Cellular Oncology Program, UPCI (1997-2001)
Steering Committee, UPCI Cancer Genetics Program (1997-)
Member, Dickson/Mellon Prize Selection Committee (1999-present)
Member, Promotions Committee, Department of Cardiology (1999-present)
Molecular and Cellular Oncology Search Committee (2002)

Graduate Students Trained	**Position**
Di Jiang	Attorney, Jenner & Block (Chicago, IL)
Zhaohui Shao	Staff Scientist, Biogen Corporation
Dan Jaffurs	University of Pittsburgh Medical School
Jennifer Siegert	Assistant Professor, University of Pittsburgh (Greensburg)
Ali Radfar	University of Pittsburgh Medical School
Eric Lechman	current
Levent Balkir	current
Zoya Shurin	current
Annahita Keravala	current
Jeff Mai	current

Postdoctoral Fellows Trained	**Position**
Nicole Osifchin, M. D.	Oncology Fellow, Oregon Health Sciences Center.
Lisa Crossley, M. D.	Research Assistant Professor, Harvard Med. Sch.
Bettina Couderc, Ph.D.	Assistant Professor, University of Toulouse, France
Leslie Doughty	Critical Care Fellow, San Antonio, Tx.
Laurence Zitvogel	Senior Staff Fellow, Institute Gustav Rousy
Jailila Adnane, Ph.D.	Research Assistant Professor, Moffitt Cancer Center, Tampa, FL
Steve Ghivizzani, Ph.D.	Assistant Professor, Harvard Medical School
John Rushton, Ph.D.	Post-doctoral Fellow, University of New Mexico
Axel Baltzer, M.D.	Assistant Professor, Dusseldorf, Germany
Andrea Gambotto, M.D.	Assistant Professor, Department of Surgery, University of Pittsburgh
Janey Whalen, Ph.D.	Research Instructor, Department of Urology, University of Pittsburgh
Nicholas Giannoukakais, Ph.D.	Assistant Professor, Department of Pathology, University of Pittsburgh
Manuel Serrano, M.D.	Madrid University
Sujing Wang, Ph.D.	Senior Research Associate, Department of Orthopaedics,
Ayman Saleh, Ph.D.	
Moira Resnick, Ph.D.	current
Zhibao Mi, Ph.D.	current
Khaleel Rehman, Ph.D.	current
Seon Hee Kim, Ph.D.	current
Qingping Yao, M.D.	current
Wentao Gao, Ph.D.	current
XiaoLi Lu, Ph.D.	current
Rajasree Menon, Ph.D.	current
James Vaughn Spencer, Ph.D.	current

Enrico Palo, M.D. current
Hiroyuki Mushiake, M.D., Ph.D. current

Extracurricular Acivities

Committees

Chair, ASGT Committee on Musculoskeletal Diseases
Member, ASGT Membership Committee

Study Sections

Ad Hoc Member of Molecular Biology and Genetics Study Section, American Cancer Society (1991).
Temporary Member, Cell Biology and Physiology (CBY2) Study Section (June, 1996)
Member, NCI Special Review Committee for the Fourth International Gene Therapy of Cancer Conference, San Diego Regional Cancer Center (1995, 1997)
Member, Army Breast Cancer Human Genetics (Gen-1) Study Section (1996-2000)
Reviewer for NIH-NINDS RFP 96-06
Temporary Member, NCI SRG Subcommittee D, Clinical Research Studies (1997, 1998)
Special Review Committee, Gene therapy approaches for cystic fibrosis and other heart, blood and lung diseases. (1997, 1998)
Special Review Committee, Gene Therapy for Hemoglobinopathies, NIH HBL (1999)
Temporary Member, PathB Study Section (1999-2000)
Member, PathB Study Section (2001-2005)
Quick Trials for Prostate Cancer Special Study Section (1999, 2000)
Urology Spore Study Section (2001)
Member, Italian Telethon Study Section (2001-2004)
Scientific Review Board, National Gene Vector Laboratory, (1998-)
Chair, Review Committee (NIDDK) "Improved methods for production of clinical gene therapy vectors for diseases of interest to NIDDK"
Juvenile Diabetes Foundation, Islet Encapsulation Grant Review (May 2000)
JDRF/Telethon Review Board (June 2002)

Site Visits

Member, AIBS Site Visit, USAMRMC Neurofibromatosis Program, Richmond, VA (May 1995)
Member, NCI PO1 Site Visit, M.D. Anderson (1997)
Member, NCI Teleconference Site Visit, University of Michigan Medical Center, (1997)
Member, NCI PO1 Site Visit, University of Michigan Medical Center, Ann Arbor, MI (1997)
Member, NCI PO1 Teleconference Site Visit, Memorial Sloan Kettering Cancer Center (1997)
Member, NCI PO1 Site Visit, City of Hope National Medical Center (1999)
Member, NIC PO1 Site Visit, Memorial Sloan Kettering (2000)
Member, JDRF Site Visit, Univ. of Pennsylvania (October, 2002)

Memberships

Member, American Association for the Advancement of Science
Member, American Society for Microbiology
Member, American Association for Gene Therapy
Member, Tissue Engineering Society
Member, American Association for Cancer Research

Editorials Boards:

Associate Editor, *Cancer Research*
Associate Editor, *Gene Therapy*
Editorial Board, *Molecular Biotechnology*
Editorial Board, *Gene Therapy and Molecular Biology*
Editorial Board, *Journal of Gene Medicine*

Editorial Board, *Cancer Gene Therapy*
Editorial Board, *Arthritis Research*
Editorial Board, *Genes & Immunity*

Consulting
Consultant; Theragen, Inc. (1992-1994)
Consultant; Genvec, Inc. (1994-1996)
Consultant, Cell Genesys (1997-1998)
Consultant, Valentis Corporation (Formerly Megabios) (1998-2002)
Scientific Advisory Board, Copernicus Gene Systems (1997-1998)
Scientific Advisory Board, Ansata Therapeutics (2002-)
Scientific Advisory Board, Orthogen, Inc (2002-)

Meetings Organized and Sessions Chaired
Session Chair, IBC Conference on Gene Therapy III (1994)
Session Chair, IBC Conference on Gene Therapy IV (1994)
Session Chair, IBC Conference on Gene Therapy V (1995)
Session Chair, 3rd DAAK/GAAC Meeting on Problems in Molecular Medicine (September 1997)
Co-Organizer, 1st Meeting on Gene Therapy for Arthritis and Related Musculoskeletal Diseases
Session Chair, 1st Meeting on Gene Therapy for Arthritis and Related Musculoskeletal Diseases
Session Chair (Connective Tissue Gene Transfer), American Society of Gene Therapy, 1999
Session Chair, Gene Therapy and the Muscoloskeletal System (September, 2000), Berne, Switzerland
Co-Organizer, 2nd International meeting on Gene Therapy for Arthritis and Related Musculoskeletal Diseases, Montepellier, France, (May, 2001)
Co-Organizer and Session Chair, Viral Gene Vectors: Molecular Biology, Design and Application to Gene Therapy, Banff, Canada (April, 2001)
Chairman and organizer, 2001 ASGT Symposium on Musculoskeletal Disorders
Session Chair, Peptide Transduction, Protein Transduction Strategies Workshop, NIH
Chairman and organizer, 2002 ASGT Education Program on Gene Transfer to Joints
Chairman and organizer, 2002 ASGT Workshop on Cartilage and Bone Healing
Co-Organizer, Rational Gene Therapy: the next five years, Banff, Canada (February, 2003)

Honors and Awards
Magill-Rhodes Scholarship, Haverford College, 1976-1980
High Honors in Biology, Haverford College, 1980
Jane Coffin Childs Memorial Fund for Medical Research Fellowship, 1986-1989
Department of Molecular Genetics and Biochemistry Faculty of the Year, 1998
Volvo Award Prize for Best Basic Science Paper in lower back pain research (1999)
North American Spine Society Award for a 1999 Outstanding Paper
Founder's Award Prize from the Eastern Orthopaedic Association for outstanding paper (1999)
Gerhard-Kuntscher-Preis 1999
Synos Research Award 2000

Teaching

1992-93

Advanced Graduate Course BIOSC 2030, MSMIC2030	14 hours
Advanced Molecular Genetics (MSMIC 2250)	2 hours
MD Training Program (MSBIO 5130)	2 hours lecture
	14 hours PBL

1993-94

Advanced Molecular Genetics (MSMIC 2355)	4 hours lecture

	2 hours conference
MD Training Program (MSBIO 5130)	9 hours PBL
Advanced Topics in Virology (Viral Vectors)	26 hours
Receptors and Signal Transduction (MSPHL)	2 hours lecture
Cancer Biology (MSMIC 2453)	1 hour lecture
Cell Biology and Physiology	2 hour lecture

1994-95

Advanced Molecular Genetics (MSMIC 2355)	4 hours lecture
	2 hours conference
MD Training Program (MSBIO 5130)	2.5 hours lecture
	11 hours PBL
Advanced Topics in Virology	3 hours lecture
Receptors and Signal Transduction (MSPHL 3510)	1.5 hours lecture
	1 hour PBL
Cancer Biology (MSMIC 2453)	2 hours lecture

1995-96

Advanced Molecular Genetics (MSMIC 2355)	4 hours Lecture
	2 hours PBL
MD Training Program (MSBIO 5130)	11 hours PBL
	2.5 hours conference
Receptors and Signal Transduction (MSPHL 3510)	1.5 hours lecture
	1 hour conference
Cancer Biology (MSMIC 2453)	1 hour lecture
Advanced Topics in Virology	12 hours lecture
	18 hours conference

1996-1997

Advanced Molecular Genetics (MSMIC 2355)	2 hours Lecture
	1 hours PBL
MD Training Program (MSBIO 5130)	3 hours lecture
	12 hours PBL
	2.5 hours conference
Receptors and Signal Transduction (MSPHL 3510)	1.5 hours lecture
	1 hour conference
Eucaryotic Molecular Genetics (MSBMG 2520)	4 hours lecture

1997-98

Advanced Molecular Genetics (MSMIC 2355)	4 hours lecture
	2 hours PBL
MD Training Program (MSBIO 5130)	1 hour lecture
	12 hours PBL
	2.5 hours conference
Eucaryotic Molecular Genetics (MSBMG 2520)	4 hours lecture
Cancer Biology (MSMIC 2453)	4 hour lecture
Advanced Topics in Virology (MSMVM)	3 hours lecture

1998-99

Advanced Molecular Genetics (MSMIC 2355)	2 hours lecture
MD Training Program (MSBIO 5130)	1 hour lecture
	12 hours PBL
	2.5 hours conference

Eucaryotic Molecular Genetics (MSBMG 2520) (Course Director)	8 hours lecture
Advanced Topics in Virology (MSMVM)	3 hours lecture
Advanced Topics in Virology (MSMVM) (Course Director)	10 hours lecture

1999-00

Advanced Molecular Genetics (MSMIC 2355)	2 hours lecture 1 Hour Discussion
MD Training Program (MSBIO 5130)	1 hour lecture
Human Genetics	1.5 hours lecture
Cancer Biology (Pathology)	3 hours Lecture
Eucaryotic Molecular Genetics (MSBMG 2520)	4 hours lecture

2000-01

Cancer Biology (MSMIC 2453)	4 hour lecture
Advanced Topics in Virology (MSMVM)	3 hours lecture
Advanced Molecular Genetics (MSMIC 2355)	2 hours lecture 1 Hour Discussion
Training Program (MSBIO 5130)	1 hour lecture
Human Genetics	1.5 hours lecture

Invited Seminars

Tufts Medical School (1989) *Regulation of transcription during stem cell differentiation*

Duke Medical School (1989) *Regulation of c-fos transcription and AP1 activity by the retinoblastoma anti-oncogene product*

University of California, Santa Cruz (1990) *Regulation of c-fos transcription and AP1 activity by the retinoblastoma anti-oncogene product*

University of Vermont (1990) *Regulation of c-fos transcription and AP1 activity by the retinoblastoma anti-oncogene product*

National Cancer Institute (1990) *Regulation of c-fos transcription and AP1 activity by the retinoblastoma anti-oncogene product*

McCardle Cancer Center, University of Wisconsin at Madison. (1990) *Regulation of transcription by the retinoblastoma anti-oncogene product*

Pittsburgh Cancer Institute (1991) *Regulation of transcription by the retinoblastoma anti-oncogene product*

University of Pittsburgh School of Medicine, Department of Pharmacology. (1991) *Regulation of transcription by the retinoblastoma gene product and p53*

University of Pittsburgh School of Medicine, Department of Human Genetics (1991) *The retinoblastoma susceptibility gene: regulation of expression and function of the gene product*

Pittsburgh Cancer Institute (1991) *The regulation of transcription by the retinoblastoma and p53 tumor suppressor gene products*

Wistar Institute (1991), Philadelphia, PA, *The regulation of transcription by the retinoblastoma and p53 tumor suppressor gene products*

Merck Cancer Research Laboratory, West Point, PA (1992) *The regulation of transcription by the retinoblastoma anti-oncogene and cyclins.*

Gene Therapy Meeting, Cold Spring Harbor Laboratory (1992) *Intraarticular expression of IL-1 receptor antagonist protein by gene transfer: gene therapy for arthritis.*

X111th European Workshop for Rheumatology Research (1993), Brighton, England, *Gene Therapy for Arthritis,*

Brookdale Laboratory for Molecular Biology, Mt Siani School of Medicine (1993) *Regulation*

of transcription by the retinoblastoma and p53 tumor suppressor gene products and cyclins

MD Anderson (1993) *Regulation of transcription by the retinoblastoma and p53 umor suppressor gene products*

New York Academy of Sciences Meeting on Gene Therapy for Neoplastic Diseases (1993), Washington D. C., *Retroviral vectors for human gene therapy*

Orthopaedic Research Society (February, 1994), New Orleans, LA, *Vectors forGene Therapy*

Gene Therapy and Immunotherapy of Cancer (February, 1994), Ein Gedi, Isreal, *Gene therapy for cancer and autoimmune diseases*

Experimental Biology Meeting (April, 1994), Anaheim, CA, *Human gene therapy - Implications in inflammation*

Cambridge Healthtech Institute Conference on Gene Therapy: New Technologies and Applications (1994), Bethesda, MD, *Gene Therapy for Inflammatory Diseases.*

IBC USA Conference on Gene Therapy (April 1994), Washington, D. C., *Gene Therapy for Arthritis.*

Multipurpose Arthritis Center Symposium, University of Michigan (May, 1994) *Viral and non-viral vectors for gene therapy of arthritis*

Burroughs-Wellcome, Research Triangle Park, N.C. (June, 1994) *Gene therapy for arthritis*

Repligen, Inc., Boston, MA (May, 1994) *Gene therapy of cancer using interleukin-12 and B7.*

Hoffman LaRoche (August, 1994) *Gene therapy for arthritis and cancer: From the laboratory to the clinic*

Symposium on Gene Therapy, Michigan State University (September, 1994) *Gene therapy for arthritis*

Magee-Womens Research Institute, Pittsburgh, PA. (1994) *Regulation of transcription by the retinoblastoma tumor suppressor protein.*

Annual Meeting of the Korean Society for Molecular Biology , Seoul Korea (October 1994) *Gene therapy for cancer and inflammatory diseases.*

IBC Conference on Gene Therapy, Washington, D.C. (November, 1994) *Gene therapy for arthritis: From the laboratory to the clinic.*

European Working Group on Human Gene Transfer and Therapy, London, England (November, 1994) *Gene therapy for arthritis.*

Wayne State University (January 1995) *Advances in Gene Therapy for Cancer and Arthritis.*

Max-Delbruck Conferences: Symposium on Gene Therapy, Berlin (April 1995) *Advances in development of gene therapies for inflammatory diseases.*

American Society for Microbiology Annual Meeting, Symposium on Immunotherapy, Washington, D. C. (May 1995), *Gene Therapy for Arthritis.*

IBC Conference on Gene Therapy, Washington, D.C. (May, 1995) *Gene therapy for inflammatory Diseases*

Howard University Workshop, DNA Technology: Gene Therapy (May 1995) *Gene Therapy for Arthritis*

Symposium on Gene Therapy, Seoul National University, Seoul, Korea (June 1995) *Immunomodulation by Gene Transfer: Development of gene therapies for arthritis and cancer.*

Samsung Medical Center, Seoul, Korea (June 1995) *Gene therapyis for arthritis and cancer*

Somatix Corporation, Alameda, CA (October 1995) *Development of gene therapies for cancer and arthritis.*

Cell Genesys, Inc., Foster City, CA (October 1995) *Immunomodulation by gene transfer: Development of gene therapies for arthritis and cancer.*

San Diego Conference on DNA, San Diego, CA (November, 1995) *Vector systems for gene therapy*

Luneburg Symposium on Interdisciplinary Approaches to Gene Therapy, Luneburg, Germany (March 1996) *Development of gene therapies for arthritis and cancer*

Seoul National University, Seoul, Korea (April 1996) *Gene therapy for arthritis and cancer*

Pasteur Institute, Paris, France (May, 1996) *Development of gene therapies for arthritis and cancer*
University of Toulouse, Toulouse, France (May, 1996) *Gene Therapy for arthritis and cancer*
Rhone-Poulenc Rorer, Paris France (May, 1996) *Gene therapy for arthritis and cancer*
University of Pittsburgh, Department of Pathology (June 1996) *Immunomodulation by gene transfer: Development of gene therapies for arthritis and cancer.*
University of Florida (June 1996) *Immunomodulation by gene transfer: Development of gene therapies for arthritis and cancer.*
Conference on Current and Future Management of Duchenne Muscular Dystrophy, Pittsburgh, PA (June 1996) *Gene Therapy for Arthritis*
Cold Spring Harbor Symposium on Cancer Genetics and Tumor Suppressor Genes (August 1996) *Regulation of Transcription by Rb and Cyclin D1 Through Interaction with TAFII250.*
University of Pittsburgh, Department of Human Genetics (September 1996) *Transcriptional regulation by the retinoblastoma tumor suppressor gene product.*
Ariad, Inc., Cambridge, MA (October 1996) *Gene therapy for arthritis.*
New York Academy of Sciences, Gene Therapy for Arthritis, New York, NY (January, 1997) *Vectors for gene therapy of arthritis.*
Moffit Cancer Center, Tampa, FL (February, 1997) *Transcriptional regulation by the retinoblastoma tand p53 umor suppressor gene product.* invited
University of Minnesota, Department of Human Genetics, (May, 1997) *Progress towards development of gene therapies for arthritis and cancer.* invited
IBC Conference on Gene Therapy: Clinical advances and Vector Development, Bethesda, MD (May 1997) *Clinical application of retroviral vectors for gene therapy of cancer and arthritis.* invited
American Red Cross, Washington, D.C. (May, 1997) , *Progress towards development of gene therapies for arthritis*
Canadian Gene Therapy Symposium, Vancouver, British Columbia. (June, 1997) *Progress towards development of gene therapies for arthritis and cancer.*
Boerhinger Ingelheim, Ridgefield, CT (July 1997) *Progress towards development of gene therapies for autoimmune diseases.*
Megabios Corp., Burlingame, CA (July 1997) *Progress towards development of gene therapies for arthritis: preclinical and clinical studies.*
Introgen Therapeutics, Houston, TX (July 1997) *Progress towards development of gene therapies for arthritis: preclinical and clinical studies.*
3rd DAAK/GAAC Meeting on Problems in Molecular Medicine: Progress in Vector Development and Application to Treatment of Human Disease by Gene Therapy, Kloster Irsee, Germany (September 1997) *Viral Vectors for gene transfer to joints*, invited
University of Toronto, Toronto, Canada (Ocgober 1997) *Progress towards development of gene therapies for arthritis preclinical and clinical studies.* invited.
IBC Conference on Arthritis, New Orleans (November 1997) *Progress towards development of gene therapies for arthritis preclinical and clinical studies.* invited.
18th Annual Meeting Japanese Society of Inflammation, Tokyo, Japan (November 1997) *Progress towards development of gene therapies for arthritis*
Japanese Rheumatism Association, Tokyo, Japan (November 1997) *Progress towards development of gene therapies for arthritis*
San Diego Conference on DNA, San Diego, CA (November, 1997) *Progress towards development of gene therapies for arthritis and cancer.*
Sloan Kettering Memorial Cancer Center (January 1998) *Gene therapy for arthritis*
University of Kentucky (April 1998) *Gene therapy for arthritis and cancer.*
Human Genome Sciences, Inc. (March 1998) *Progress towards development of gene therapies for arthritis Preclinical and clinical studies.* invited.

Symposium on Tissue Engineering Cryo 98, Pittsburgh, PA (July, 1998) *New advances in gene therapy for arthritis*. Invited

American Society for Gene Therapy, Seattle, Washington (May 1998) *Gene therapy for arthritis*, Invited.

International Conference on Gene Therapy and Molecular Biology, Crete, Greece (August, 1998) *Gene therapy for arthritris: preclinical and clinical studies.* Invited.

Symposium on Gene Therapy, Seoul, Korea (October, 1998) *Gene transfer to block inflammation and facilitate transplantation*,

1st Meeting on Gene Therapy for Arthritis and Related Musculoskeletal Diseases, Washington, DC, (December, 1998)*Meeting Summary*

University of Alabama at Birmingham (April 1999) Immunomodulation by Gene Transfer: Recent progress towards treating autoimmune diseases and cancer by gene therapy

University of Pittsburgh, Department of Molecular Genetics and Biochemistry, Faculty of Year Lecture (April 1999) Immunomodulation by gene transfer: Progress towards development of gene therapies for autoimmune disease and cancer.

2nd International Workshop on IL-10, Milan, Italy (May 1999) *Progress toward development of IL-10-mediated gene therapies for arthritis and cancer.*

4th World Congress on Inflammation, Paris, France (June 1999) *Gene transfer to joints: Development of novel animal models and therapies for arthritis.*

AO Meeting on Orthopaedic Gene Therapy, Davos, Switzerland (September 1999) *Overview – Orthopaedic Gene Therapy*, invited

1999 American College of Rheumatology Annual Meeting, Frontiers in Basic Research Course – Gene Therapy, Boston, MA (November 1999) *Gene transfer to joints: progress towards development of a gene therapy for arthritis.*

1999 American College of Rheumatology Annual Meeting, Boston, MA (November 1999) *Results of a Phase I trial gene therapy trial for arthritis.*

SmithKline Beechum, Malvern, PA (November, 1999) *Gene therapy for arthritis*

National Institutes of Health, Besthesda, MD (November, 1999) *Immunomodulation by gene transfer: progress towards development of gene therapies for autoimmune diseases and cancer.*

Japanese Society for Biological Therapy, Yokohama, Japan (December 1999) *Immunomodulation by gene transfer: Progress towards development of gene therapies for cancer and arthritis.*

Pittsburgh Orthopaedic Tissue Engineering Symposium, Pittsburgh, PA (April 2000) *Gene therapy approaches for treating bone and joint disorders*, invited

University of Vermont, Burlington, VT, (April, 2000) Progress towards development of gene therapies for autoimmune diseases and cancer; Pre-clinical and clinical studies.

Pacific West Cancer Fund Symposium, Pittsburgh, PA (May 2000) Peptide Mediated Delivery of Proteins for Cancer Therapy.

American Society of Transplantation, Chicago, Illinois (May, 2000) *Gene therapy for transplantation.*

15th Annual Orthopaedic Research Meeting of the Japanese Orthopaedic Association, (September, 2000) Kyoto, Japan

Kyoto Prefectural University, Kyoto, Japan (September, 2000) *Transcriptional regulation by Rb.*

Gene Therapy and the Muscoloskeletal System (September, 2000), Berne, Switzerland, *Gene therapy for arthritis: preclinical studies.*

American Society for Histocompatibility and Immunogenetics, (October, 2000) Orlando, FL, *Gene therapy for autoimmune diseases and transplantation.*

Cytokines and Cancer, AACR Meeting in Vail, CO (September, 2000) *IL-10 and IL-10 homologues in cancer.*

Duquesne University, Pittsburgh, PA (October, 2000) *Gene and protein based therapies for arthritis and cancer.*

Maxygen, Redwood City, California, (December 2000) *Gene and protein-based therapies for autoimmune disease, cancer and viral infection.*

University of Massachusetts Medical School, Worcester, MA (January, 2001) *Progress toward development of gene and protein based therapies for autoimmune diseases and cancer: Prelinical and clinical studies.*

Dartmouth Medical School, Hanover, NH (March, 2001) *Gene and protein based therapies for autoimmune diseases and cancer.*

LSU, New Orleans (February, 2001) *Gene therapy for cancer and autoimmune diseases*

Deltagen, Redwood city, California (March, 2001) *Peptide-mediated protein delivery for treatment of arthritis and cancer.*

University of Pittsburgh, Department of Environmental Health and Molecular Toxicology, (March, 2001) *Progress toward development of gene and protein based therapies for autoimmune diseases and cancer: Prelinical and clinical studies.*

Viral Gene Vectors: Molecular Biology, Design and Application to Gene Therapy (April, 2001), Banff, Canada, *Gene therapy for arthritis*, invited

Eye and Ear Institute, Pittsburgh, PA (April, 2001) *Immunomodulation by gene transfer.*

American Association of Orthopaedic Surgeons, San Francisco (March, 2001) *Gene therapy for orthopaedic applications*

ASM meeting on Viral Gene Vectors: Molecular Biology, Design and Application to Gene Therapy, Banff, Canada (April, 2001) *Gene therapy for arthritis*

2nd International Meeting on Gene Therapy for Arthritis and Related Disorders, Montpellier, France (May 2001) *Viral and peptide mediated intra-articular transfer of genes and proteins*

2nd International Meeting on Gene Therapy for Arthritis and Related Disorders, Montpellier, France (May 2001) *Update on the contralateral effect in rabbit and mouse models.*

Valentis Symposium, 4th Annual Society for Gene Therapy Meeting, Seattle, WA (May 2001) *Delivery of Apoptotic Genes for the Treatment of Arthritis*

Genzyme Corporation, Framingham, MA (August, 2001) Gene therapy for arthritis: Preclinical and clinical studies.

NIH workshop on Orthopaedics, Scottsdale, AZ (September, 2001) *Vectors for Gene Transfer*

Avigen, Inc., San Francisco, CA (August, 2001) *Gene therapy for arthritis.*

Carnegie Mellon University, Pittsburgh, PA (September, 2001) *Gene therapy for acquired diseases: current status and future directions.*

Grand Rounds, University of Massachusetts Medical Center, Department of Medicine (October 2001) *Gene therapy for arthritis: Preclinical and Clinical Studies.*

Pulmonology Grand Rounds, University of Pittsburgh, (October 2001) *Gene therapy for arthritis: Preclinical and Clinical Studies.*

Institute for Human Gene Therapy, University of Pennsylvania, (October, 2001) *Gene and protein based therapies for autoimmune diseases and cancer.*

University of South Florida, Tampa, FL (October, 2001) *Gene therapy for arthritis*

Focus on Diabetes, Erice, Sicily (December, 2001) *Gene therapy for Diabetes.*

University of Michigan, Ann Arbor, MI (January, 2002) *Gene and protein based therapies for autoimmune diseases and cancer*

National Cancer Institute, Protein Transduction Strategies Workshop, (February, 2002) *Characterization and optimization of peptide mediated transduction*

Roswell Park Cancer Center, Buffalo, NY (March 2002) *Gene and protein based therapies for autoimmune diseases and cancer: Preclinical and Clinical studies.*

Eli Lilly Pharmaceuticals (February, 2002) *Animal models of arthritis for the analysis of gene and proteins based therapies*

Locus Discovery, Philadelphia, PA (April, 2002*) Animal models of arthritis for the analysis of gene and proteins based therapies*

Seoul National University Symposium on Gene Therapy (May, 2002) *Gene and protein based therapies for arthritis: Preclinical and clinical studies.*

4th Annual American Society of Gene Therapy Meeting, Boston, MA (June, 2002) *Gene transfer to joints*

7th JDRF Meeting on Diabetes, Oxford, England (August, 2002) *Gene and protein based strategies to facilitate islet transplantation.*

2nd Annual Meeting of the Federation of Clinical Immunology Societies, San Franciso, CA (July, 2002) *Gene therapy for arthritis.*

15th Naito Conference on Molecular Biological Approaches for Intractable Diseases, Tokyo, Japan (October, 2002) Invited

Annual Meeting of the American College of Rheumatology, New Orleans, LA (October, 2002) Invited

Clinical Protocols

1. Gene Therapy for Gaucher Disease: Ex Vivo Gene Transfer and Autologous Transplantation of $CD34^+$ Cells. Co-Investigator. Principal Investigator, John A. Barranger; Initiated 9/95

2. Clinical trial to assess the safety, feasibility, and efficacy of transferring a potentially anti-arthritic cytokine gene to human joints with rheumatoid arthritis. Co-Principal Investigator. Principal Investigator, Chris H. Evans. Complete

3. IL-12 gene therapy using direct injection of tumors with genetically engineered autologous fibroblasts. Co-Principal investigator. Prinicipal Investigators, Hideaki Tahara, Michael T. Lotze; Completed.

4. IL-12 gene therapy for patients with cancer using direct injection of tumors with genetically engineered autologous dendritic cells (Phase I/II). Co-investigator. H. Tahara, Principal Investigator.

5. Phase II trial of IL-12 gene therapy for head and neck cancer using direct injection of tumors with genetically engineered autologous fibroblasts. Co-investigator. M. Lotze, Principal Investigator,

6. IL-12 gene therapy for melanoma using direct infection of tumors with genetically engineered autologous fibroblasts (phase II study). Co-investigator. M. Lotze, Principal Investigator.

7. Gene therapy of malignant gliomas: A phase I study of IL-4-HSV-TK gene modified autologous tumor to elicit an immune response. Co-investigator. I. Pollack, Principal Investigator.

Patents

Retroviral Vectors Useful for Gene Therapy. Inventors: P. Robbins, B. Guild, L. Rafield, L. Cohen and R. Mulligan. Somatix Therapy Corporation. Australian Patent No. 659824. Issued 9-19-95

IRAP gene as a treatment for arthritis Inventors: J. C. Glorioso, C. H. Evans, and P. D. Robbins. University of Pittsburgh. United States Patent #5,858,355, January 12, 1999

Gene transfer for studying and treating a connective tissue of a mammalian host Inventors: J. C. Glorioso, C. H. Evans, and P. D. Robbins. University of Pittsburgh. United States Patent #6,156,304, December 5, 2000

Viral vectors to inhibit leukocyte infiltration or cartilage degradation of joints Inventors: J. C. Glorioso, C. H. Evans, P. D. Robbins and S. C. Ghivizzani. University of Pittsburgh. United States Patent #6,159,464, December 12, 2000

Gene Therapy for Gaucher Disease. Inventors: J. Barranger and P. Robbins. University of Pittsburgh, Issued.

Systemic gene treatment of connective tissue diseases with IRAP-1. Inventors: C. H. Evans and Paul D. Robbins. United States Patent #5,766,585 June 16, 1998

Retroviral Gene Therapy Vectors and Therapeutic Methods Based Thereon. Inventors: I. Riviere, L. K. Cohen, B. Guild, L. Rafield, P. Robbins, and R. Mulligan. Somatix Therapy Corporation. PCT Publication No WO 95/34669.

Applications

Genetic Modification of Endothelial Cells. Inventors: R. Mulligan, L. Birinyi, A. D. Callow, L. K. Cohen, B. C. Guild, L. F., P. Robbins and J. Wilson. Somatix Therapy Corporation. Priority US 607,252. Abandoned.

Gene Treatment of Arthritis. Inventors: J. C. Glorioso, C. H. Evans, and P. D. Robbins. University of Pittsburgh. Priority US 07/630,981

A cytoplasmic gene expression system which utilizes a prokaryotic RNA polymerase autogene. Inventors: L. Huang, P. Robbins, D. Jaffurs, M. Brisson, S. Li, and J. Yang. Priority US 2710-4003.

Gene Transfer to intervertebral disc cells. Inventors: J. Kang, K Nishida, C. Evans and P. Robbins. University of Pittsburgh 9/199,978

Gene transfer to islets to inhibit dysfunction and block apoptosis. Inventors: P. Robbins, M. Trucco and N. Giannoukakis.

Identification of peptides that facilitate uptake and nuclear transport of proteins, DNA and viruses. Inventors: P. Robbins, Z. Mi, and R. Frizzell

Cartilage repair gene therapy. Inventors: C. Evans, S. Ghivizzani, and P. Robbins

The use of oligodeoxyribonucleotide decoys to modify antigen presenting cells as a means of inhibiting immune stimulation. Inventors: P. Robbins, L. Lu and N. Giannoukakis.

Viral and non-viral vectors as vehicles for delivering transgenes for treating bone pathologies Investors: A. Baltzer, C. Evans, and P. D. Robbins, US Patent Applications 09/561,524.